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**SECTION 5 - 510(k) Summary** (21 CFR 807.92)

**510(k) Number K_____**

| | | |
|---|---|---|
| 1 | Submission Owner | DENTIN® Implants Technologies Ltd.<br>Shai Hagbi – CEO<br>Migdal Tefen Industrial Park,<br>P.O. Box 10, ZIP 24959<br>ISRAEL<br>Phone: 972-77-4408470<br>Fax: 972-4-9941011 |
| 2 | Official Correspondent Contact Person | Sterling Medical Registration<br>Daniela Levy - Regulatory Consultant<br>22817 Ventura blvd. #161<br>Woodland Hills, CA 91364<br>Phone: 1-213-787-3026<br>Fax: 1-818-456-4222<br>Web www.sterlingmedicalregistration.com |
| 3 | Submission Date | February 2012 |
| 4 | Device Trade Name | DENTIN® Dental Implants System |
| 5 | Regulation Description | Root-form Endosseous Dental Implants and Abutments |
| 6 | Classification form | Device Name : Implant, endosseous, root-<br>Product Code : DZE<br>Subsequent product code: NHA<br>Regulation No : 872.3640<br>Class : II<br>Panel : Dental |
| 7 | Reason for the Premarket Notification Submission | : New Device |
| 8 | Identification of Legally Marketed Predicate Devices | : |

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DENTIN® Dental Implants System is substantially equivalent to Alpha-Bio Tec K063364; MIS Implant Technologies Ltd K003191, K103089, K080162; NOBELREPLACE K023113, K062566; Implant Direct SwissPlant K081396 in terms of intended use, indication for use, technological characteristics, performance and user interface.

DENTIN® PEEK Abutments are substantially equivalent to; CAMLOG® Abutments PS K090347 in terms of intended use, indication for use, technological characteristics, performance and user interface.

The predicate devices are a Class II medical device.

9 Device Description:

DENTIN® Dental Implants System consists of one and two stage endosseous form dental implants, internal hexagonal and one piece implants system; cover screws and healing caps; abutment systems and superstructures; impression copy system & surgical instruments.

Two stage, Internal hex implants:-

CLASSIC implants are provided in diameters: 3.3, 3.75, 4.2, 5 & 6 with lengths, 7 (only to 5&6 dm), 8, 10, 11.5, 13, & 16 (only to 3.3, 3.75&4.2 dm)

RAPID implants are provided in diameters: 3.3, 3.75, 4.2, 5 & 6 with lengths 7 (only to 5&6 dm) 8, 10, 11.5, 13, & 16 (only to 3. .3, 3.75&4.2 dm)

PRESTIGE implants are provided in diameters: 3.75, 4.2, 5 & 6, with lengths 7 (only to 5&6 dm), 8, 10, 11.5, 13, & 16 (only to 3.75&4.2 dm)

One stage, one piece implants:-

ONEPIECE implants are provided in diameters 3.0, 3.3 with lengths 10, 11.5, 13, & 16

Healing caps are available in 3 sizes: Standard, Narrow and Wide with Heights: 1, 2, 3, 4, 5, 6 and 7 mm.

DENTIN Abutments system provides: Ball abutment (angulated), Titanium abutment (slim, straight, angulated), Anatomic titanium abutment (straight, angled), Leaf titanium abutment, Plastic abutment (wide, direct), Titanium castable abutment, Esthetic connection abutment, Angular curve (narrow three, regular three, wide), Angular smooth (minor, thin, wide), Ball minor (angular, straight), Aesthetic connection abutment (minor regular, multi, wide), Angular multi unit, Gauge angle, Immediate temporary conical, Straight curve (narrow three, regular

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three, wide), Straight (level minor, slim minor), Wise click (angular multi, connection, minor).

Impression copy system consists of: Transfers, Analogs & Accessories and Transfers.

10 Intended use / Indication for Use:

DENTIN® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Two Stage Implants: CLASSIC, RAPID, PRESTIGE.

One Stage Implants: ONE PIECE

DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants.

11 Performance Standards or Special Controls :

- ISO 7405 Second edition 2008-12-15 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.
- ISO 5832-3:1996 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.
- ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants.
- FDA guidance document: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff.

12 Substantial Equivalence :

| Substantial Equivalent Table | DENTIN Implants: CLASSIC, RAPID, PRESTIGE | Uno Narrow Implant | NobelReplace | MIS System - SEVEN Internal Hex Implants | Dualfit Internal Hex Implants DFI |
|---|---|---|---|---|---|
| ***510k*** | | **(K080162)** | **(K023113, K062566 )** | **( K003191, K103089 K080162)** | **(K063364)** |
| Indication for Use | DENTIN® Dental Implants System | The UNO Narrow Implant is | The Nobel Biocare Replace | The MIS implant system is | The Alpha-Bio Dental Implant |

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| | is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. DENTIN® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Two Stage Implants: CLASSIC, RAPID, PRESTIGE. One Stage Implants: ONE PIECE DENTIN® ONEPIECE Implants 3.0 mmd are intended for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants. | indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by adjacent teeth and roots, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more 03.0 mm implants adjacent to one another. The UNO Narrow Implant is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate. | Tiunite Endosseous Implant is intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth, and to restore patient's chewing function. This may be accomplished using a two stage surgical procedure or a single stage surgical procedure. If the single stage surgical procedure is used, these implants may be loaded immediately following insertion – provided – at least four implants are placed and splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foraminae) where good initial stability of the implants with or without bi-cortical anchorage, can most often be obtained. | indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. | System® is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Two stage: ATID, DFI,SPI,SFB,ATIE OF, ITO, SPR One stage: ITO, SPR One stage and One Piece: ARRP, ARPB, ARRC 3mmd diameter are intended only for placement at the mandibular central and lateral incisors and maxillary and lateral incisors. Indicated also for denture stabilization using multiple implants One stage and One Piece for temporary use: ARR, ARB, ARS, ARSB permit immediate splint stability for crown, bridge and prosthesis, protect graft sites. The Alpha-Bio Dental Implant System® is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading. DFI, SPI, ARRP, ARPB. The Alpha-Bio Dental Implant System® is indicated also for |

| | | | | | |
|---|---|---|---|---|---|
| | | | | | immediate loading on single tooth when good primary stability is achieved and with appropriate occlusal loading. SPI, SFB. All implants with diameter 3.3mmd should not use angled abutment. |
| Material | GR-5 Titanium Ti-6Al-4V ELI | GR-5 Titanium Ti-6Al-4V ELI | CP4 Titanium | GR-5 Titanium Ti-6Al-4V ELI | GR-5 Titanium Ti-6Al-4V ELI |
| Implant Body Contour | Tapered | Tapered | Tapered | Tapered | Tapered |
| Anatomical Site | Oral Cavity | Oral Cavity | Oral Cavity | Oral Cavity | Oral Cavity |
| Principle of operation | Conventional procedure | Conventional procedure | Conventional procedure | Conventional procedure | Conventional procedure |
| Self tapping | ✓ | ✓ | ✓ | ✓ | ✓ |
| Sterilization | Gamma Ray | Gamma Ray | Gamma Ray | Gamma Ray | Gamma Ray |
| Packaging | Double packaging | Double packaging | Double packaging | Double packaging | Double packaging |

Summary of Equivalence:

DENTIN® Dental Implants System shares similarity to Alpha-Bio Tec K063364; MIS Implant Technologies Ltd K003191, K103089, K080162; NOBELREPLACE K023113, K062566; in terms of intended use, indication for use, design, technological characteristics, performance and user interface. DENTIN® Dental Implants System shares the same raw material as its predicated devices, the only difference whereas NOBELREPLACE uses pure titanium commercial DENTIN® and the other predicate devices uses titanium alloy, the differences raise no new issues of safety or effectiveness than the predicate devices.

Mechanical Testing - DENTIN® Implants Technologies has conducted Fatigue – Static & Cycling tests which comply with ISO 14801 Second edition 2007-11-15 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The test results have demonstrated the high resistance and high ability with the use of DENTIN Dental Implant System. Therefore, DENTIN® Dental Implants System raises no new issues of safety or effectiveness than the predicate devices.

Safety & Effectiveness testing - sterilization validation tests, shelf life testing were conducted in order to ensure safety and effectiveness related to DENTIN® Dental Implants & Abutments system. Test results have demonstrated that the SAL of $10^{-6}$ was

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achieved and all testing requirements were met. Thus, DENTIN® Dental Implants System raises no new issues of safety or effectiveness than the predicate devices.
Risk Assessment was conducted and has demonstrated no new safety and/or effectiveness issues than the predicate devices.

Conclusion:

As verified by clinical and non clinical data, bench testing, mechanical testing, risk assessment and substantial equivalence, DENTIN® Dental Implant System shares similarity with its predicated devices by term of intended use, raw material and technical design. The fundamental scientific technology of the device is identical or very similar to the referenced predicate devices, thus DENTIN® Dental Implant System is considered to be substantially equivalent to its predicate devices and raises no new safety and/or effectiveness issues than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dentin Implants Technologies, Limited
C/O Ms. Daniela Levy
Regulatory Consultant
Sterling Medical Registration
22817 Ventura Boulevard #161
Woodland Hills, California 91364

JUL 5 2012

Re: K120530
Trade/Device Name: DENTIN® Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 10, 2012
Received: June 12, 2012

Dear Ms. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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**SECTION 4 - Indication for Use Statement**

**Indications for Use**

**Indications for Use**

510(k) Number (if known): _____

Device Name:

DENTIN® Dental Implants System

Indications for Use:

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Prescription Use _✓__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120530